Year	Details of projects	Amount Approved	Amount Released	Status of the project
	Indoor Stadium at Fatehbad Hyderabad.	60.00	60.00	Project completed
	Indoor Stadium at Gachibowli Hyderabad	60.00	60.00	-do-
	Outdoor Stadium at Gachibowli, Hyderabad	18.00	18.00	-do-
	Indoor Stadium at Yousufguda, Hyderabad	60.00	60.00	-do-
	Cycle Velodrome at Hyderabad	24.00	24.00	-do-
	Swimming Pool at Gachibowli, Hyderabad	60.00	60.00	-do-
	Indoor Stadium at Saroor Nagar, Hyderabad	60.00	60.00	-do-
	Swimming Pool at Warangal	53.17	47.85	Not yet completed
	Swimming Pool at Nizamabad	25.00	17.50	-do-
	Indoor Stadium at Karamchedu Distt. Prakasam	18.317	4.577 (final grant)	Project completed

WRITTEN ANSWERS TO STARRED AND UNSTARRED QUESTIONS SET FOR THE 11TH AUGUST, 2003*

Clearance to new drugs

*301. SHRI KHAN GHUFRAN ZAHIDI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that the number of new drugs cleared during this year has come down as compared to the last year; and

(b) if so, the reasons therefor and the details of new drugs cleared so far?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) and (b) Based on the overall evaluation and submission of all required data, 51 New Drug molecules were approved and 800 subsequent approvals were granted in the calendar year 2002. Similarly, 14 New Drugs molecules have been

*The sitting of the Rajya Sabha on Monday, the 11th August, 2003 was cancelled. Answers to Questions put down in the lists for that day were laid on the Table of the House on Wednesday, the 13th August, 2003.

approved and 400 subsequent New Drug Approvals (SNDA) were granted during the period January, 2003 to July, 2003. Details are given in the Statement (*See* below). As the figures for 2003 are up to July 2003, they are not comparable with last year's figures.

The requirements for granting New Drug approval are specified in Rules, 122-A to 122-E and Schedule-Y of Drugs & Cosmetics Rules. The evaluation of New Drugs is a complex process and varies according to the nature of the molecule/drug. Approval process of New Drugs includes examination of chemical and pharmaceutical information, data on pre-clinical/clinical trials for safety and eficacy of the drug generated abroad as well as in Indian population, bio-equivalence study, stability and dissolution study reports, Central Drugs Laboratories Test reports for validation of test protocol and specification of the drug, consultation with experts etc. Therefore, yearly statistics may not be comparable.

Statement

New drugs approved during January to December 2002

Sl. No	Name of Drug	Classification	Date of Approval
1.	Meropenem Inj.	Antibacterial	08-01-02
2.	Bimatoprost (Opthalmic)	Anti-Glaucoma	08-01-02
3.	Fosinopril Sodium	Anti-Hypertensive	10-01-02
4.	Montelucast Sodium	Anti-Asthmatic	
5.	Thymogen Inj.	Anti-Cancer	12-02-02
6.	Mifepristone	Progesterone Antagonist (For M.T.P.)	13-02-02
7.	Dexarazoxane inj.	Cardio Protective Agent	26-02-02
8.	Tranexamic Acid.	Anti-Fibrinolytic	06-03-02
9.	Bicalutamide	Anti-Cancer	07-03-02
10.	Apraclonidine Opthalmic	α-2 Adrenergic Agonist	15-03-02
11.	Mizolastine	Anti-Allergic	15-03-02
12.	Miltefosine	For Kala-azar	15-03-02
13.	Loteprednol Etabonate Opthalmic	anti-inflammatory Ophth	15-03-02
14.	Ziprasidone HCL	For Schizophrenia	18-03-02
15.	ABACAVIR	Anti-HIV	22-03-02

Sl. No.	Name of Drug	Classification	Date of Approval
16.	Nadifloxacin Cream	Anti-bacterial	28-03-02
17.	Tamsulosin HCL	For BPH	04-04-02
18.	Famiciclovir	Anti viral	11-04-02
19.	Nateglinide	Anti-Diabetics	01-05-02
20.	Lercanidine HCL	Anti-Hypertensive	07-05-02
21.	Itopiride	Gastro Prokinetic Agent	09-05-02
22.	Alprostadil Inj.	For Erectile Dysfunction	08-05-02
23.	Vinpocetine	Vasodilator	13-05-02
24.	Quetiapine Fumerate	Anti-Psychotic	31-05-02
25.	Isotretinoin Soft Gel Caps.	For Acne Vulgaris	21-06-02
26.	Nebivolol Tab.	Anti-Hypertensive	12-07-2002
27.	Sirolimus	Immunosuppressant	15-07-2002
28.	Drotrecogin alpha (activated)	For severe Sepsis	23-07-2002
29.	Pygenum Africanum	For Benign prostatic hypertrophy	30-07-2002
30.	Valdecoxib	NSAID	01.08.2002
31.	Thalidomide	For Leprosy	12.08.2002
32.	S(-) Amlodipine Besylate	Anti-Hypertensive	16.08.2002
33.	Cabergoline	For Hyperprolactinemia	05.09.2002
34.	Butorphanol Tartrate	Opiod Analgesic	11.09.2002
35.	Gemtuzumab	For Myeloid Leukemia	12.09.2002
36.	Quinapril	Anti-Hypertensive	19.09.2002
37.	Valacyclovir	Anti-Viral	25.09.2002
38.	Ceftiofur Sodium & Ceftiofur HCl	Anti-Biotic (For Veterinary Use)	08.10.2002
39.	Fosphenytoin Sodium	Anti-Epileptic	01.10.2002
40.	Metaxolone	Muscle relaxant	08.10.2002
41.	Acamprosate Calcium	For Alcohol Dependency	30.10.2002
42.	Cefepime HCl	Anti-Biotic	30.10.2002
43.	Tegaserod Maleate	For Irritable Bowel Syndrome	01.11.2002

1	2	3	4
44.	Aztreonam	Anti-Bacterial	01.11.2002
45.	Parecoxib	NSAID	01.11.2002
46.	Balsalazide Disodium	For Ulcerative Colitis	12.11.2002
47.	Cefetamet Pivoxil	Anti-Bacterial	14.11.2002
48.	Telmisartan	Anti-Hypertensive	25.11.2002
49.	Levocetrizine	Anti-Histaminic	12.12.2002
50.	Poractant ∝	For respiratory distress in preterm babies	24.12.2002
51.	Reboxetine	Anti-depressant	31.12.2002

New Drugs under rule 122-A and 122-B/C during the period of January, 2003 to July, 2003

Sl.No.	Name of the Drugs	Category	Date of approval
1.	Cefprozil	Antibiotic	10.1.2003
2.	Cilostzol	For intermittent claudication	23.1.2003
3.	Escitalopram Oxalate	Anti depressant	24.1.2003
4.	Anastrazole	Anti cancer	10.2.2003
5.	Rizapriptan	Anti migrain	27.2.2003
6.	Gadobenate (Dimeglu mine IV injection)	MRI Contrast Medium	07.3.2003
7.	Tacdrolimus Ointment	Immuno-modulator	10.3.2003
8.	Metolazone	Diuretic	23.4.2002
9.	Tiotropium Bromide	Anti asthematic	16.4.2003
10.	Gadoversetamide Injection	MRI Contrast Medium	04.6.2003
11.	Torsamide	Diuretic	09.06.2003
12	Cyproterone Tablet	For Prostatic Cancer	10.6.2003
13.	Aripiprazole	Anti schizophrenia	11.6.2003
14.	Bendrofluazide	Diuretic	24.7.2003